IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Michael P. WALLACE** **Serial No.: 10/669,203** **Filed:** September 23,2003 **For:** ENERGY ACTIVATED VASO-OCCLUSIVE DEVICES	**Group Art Unit:** 3739 **Confirmation No.:** 2638 **Examiner:** Roane, Aaron F.

RESPONSE TRANSMITTAL

M/S: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. Documents Enclosed:

Transmitted herewith for the above-identified application are the following:

☒ RCE (2 pages);

☒ Amendment and Response to Final Office Action (14 pages);

☒ Information Disclosure Statement (4 pages) with 3 NPL references

☒ Transmittal letter with certificate of EFS WEB transmission (2 pages).

CERTIFICATE OF TRANSMISSION

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to the Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below via the USPTO EFS-Web filing system.

October 25, 2007
Date of Deposit

/MaritzaKidd/
Maritza Kidd

2. Request for EXTENSION OF Time:

The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply.

☒ If any extension fee is required, please consider this a petition therefor.

3. RCE FEES

☒ **RCE FEE:** 37 CFR §1.17 (e)	$810.00
Reduction by ½ for Filing by Small Entity. Note 37 CFR § 1.9, 1.27, 1.28. ☐	$0.00
Extension of Time (from above)	$0.00
TOTAL FEES SUBMITTED HEREWITH	$810.00

4. Method of Payment of fees:

☒ Credit card payment in the amount of $810.00 is charged herein via EFS-Web filing system.

☐ Charge Vista IP Law Group LLP Deposit Account No. **50-1105** in the amount of **$0.00**.

☒ The Commissioner is authorized to charge Vista IP Law Group LLP Account No. **50-1105** for any fees required under 37 CFR §§ 1.16, 1.17 and 1.445 that are not covered, in whole or in part, and to credit any overpayments to said Deposit Account No. **50-1105**

Respectfully submitted,
VISTA IP LAW GROUP LLP

Dated: 10-25-07

By: David Burse
David T. Burse
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PTO/SB/30EFS (05/07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	10669203	Filing Date	2003-09-23	Docket Number (if applicable)	03-247 (US01)	Art Unit	3739
First Named Inventor	Michael P. Wallace			Examiner Name	Aaron F Roane		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 501105

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Signature of Registered U.S. Patent Practitioner			
Signature	David T Burse	Date (YYYY-MM-DD)	2007-10-25
Name	David T. Burse	Registration Number	37104

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Docket No.: 03-247 (US01)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	
Michael P. WALLACE	**Group Art Unit:** 3739
Serial No.: 10/669,203	**Confirmation No.:** 2638
Filed: September 23,2003	**Examiner:** Roane, Aaron F.
For: ENERGY ACTIVATED VASO-OCCLUSIVE DEVICES	

AMENDMENT AND RESPONSE TO OFFICE ACTION

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In connection with the Request for Continued Examination (RCE) filed herewith and in response to the final office action mailed July 25, 2007, please consider the following amendments and remarks.

Amendments to the Claims are reflected in the listing of claims, which begins on page 2.

Remarks begin on page 9.

LISTING OF THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A vaso-occlusive device for treating a site within a patient's vasculature, comprising:

a first material which, if the device is detached from a delivery catheter and implanted at a treatment site in the patient's vasculature, may be heated by application of energy transmitted by an ~~source of~~ energy emitting element located external to the patient; and

a bioactive agent that, if the device is detached from a delivery catheter and implanted at a treatment site in the patient's vasculature, is released from the device into the treatment site upon heating of the device by application of energy transmitted by said external energy ~~source~~ emitting element to heat the first material.

2. (Currently Amended) The vaso-occlusive device of claim 1, further comprising a second material having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the device when the first material is heated by the energy transmitted by the external energy ~~source~~ emitting element.

3. (Currently Amended) The vaso-occlusive device of claim 2, wherein the second material is embedded in one or more portions of the device, such that, if the device is detached from a delivery catheter and implanted at the treatment site when heated by

the energy transmitted by the external energy ~~source~~ emitting element, and thereafter allowed to cool at the treatment site, the one or more portions are at least partially melted and fused together to thereby stabilize the vaso-occlusive device in a deployed configuration.

4. (Withdrawn) The vaso-occlusive device of claim 2, the second material comprising a coating provided on at least a portion of the device.

5. Canceled.

6. (Previously Presented) The vaso-occlusive device of claim 2, wherein said bioactive agent is released by at least partially melting said second material.

7. (Currently Amended) The vaso-occlusive device of claim 1, the first material comprising a ferrous material, and the external energy ~~source~~ emitting element comprising a magnetic resonance system.

8. (Original) The vaso-occlusive device of claim 1, wherein the first material is embedded in the device.

9. (Withdrawn) The vaso-occlusive device of claim 1, wherein the first material is in a coating provided on at least a portion of the device.

10. (Original) The vaso-occlusive device of claim 1, the device comprising

a coil forming a lumen, and

a heating member disposed in the lumen, the heating member at least partially comprising the first material.

11. (Original) The vaso-occlusive device of claim 10, the heating member comprising a filament attached to first and second locations of the coil.

12. (Previously Presented) The vaso-occlusive device of claim 10, further comprising a second material having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the heating member when the first material is heated by the external energy source.

13. (Previously Presented) The vaso-occlusive device of claim 12, wherein the second material is embedded in one or more portions of the coil, such that, if the coil is implanted at the treatment site when heated by the heating member, and thereafter allowed to cool at the treatment site, the one or more portions are at least partially melted and fused together to thereby stabilize the coil in a deployed configuration.

14. (Withdrawn) The vaso-occlusive device of claim 12, the second material comprising a coating provided on at least a portion of the coil.

15. Canceled.

16. (Withdrawn) The vaso-occlusive device of claim 12, the heating member comprising a filament attached to the coil, the second material comprising a coating provided on at least a portion of the filament.

17. Canceled.

18. (Currently Amended) A vaso-occlusive device for treating a site within a patient's vasculature, comprising:

a helically wound coil comprising a highly conductive material and forming a lumen;

a filament at least partially positioned in the lumen, the filament comprising a ~~highly resistive~~ ferrous material, such that, if the device is detached from a delivery catheter and implanted at a treatment site in the patient's vasculature and exposed to a pulsed magnetic field applied from an energy emitting element located outside the body, the ~~highly resistive~~ ferrous material is heated; and

a bioactive agent that, if the device is detached from a delivery catheter and implanted at a treatment site in the patient's vasculature, is released from the device upon heating of the device by application of said pulsed magnetic field ~~to heat the first material~~.

19. (Currently Amended) The vaso-occlusive device of claim 18, the highly conductive material comprising platinum~~, the highly resistive material comprising ferrous material~~.

20-24. Canceled.

25. (Currently Amended) The vaso-occlusive device of claim ~~19~~18, wherein the ferrous material is embedded in the filament.

26. (Currently Amended-Withdrawn) The vaso-occlusive device of claim ~~19~~18, wherein the ferrous material is in a coating provided on at least a portion of the filament.

27-36. Canceled.

37. (Currently Amended) A vaso-occlusive device for treating a site within a patient's vasculature, comprising:

a first material which, if the device is detached from a delivery catheter and implanted at a treatment site in the patient's vasculature, may be heated by application of energy transmitted by an ~~source of~~ energy emitting element located external to the patient; and

a bioactive agent that, if the device is detached from a delivery catheter and implanted at a treatment site in the patient's vasculature, is activated upon heating of the device by application of energy transmitted by said external energy ~~source~~ emitting element to heat the first material.

38. (Currently Amended) The vaso-occlusive device of claim 37, the first material comprising a ferrous material, and the external energy ~~source~~ emitting element comprising a magnetic resonance system.

39. (Previously Presented) The vaso-occlusive device of claim 37, wherein the first material is embedded in the device.

40. (Previously Presented-Withdrawn) The vaso-occlusive device of claim 37, wherein the first material is in a coating provided on at least a portion of the device.

41. (Previously Presented) The vaso-occlusive device of claim 37, the device comprising

a coil forming a lumen, and

a heating member disposed in the lumen, the heating member at least partially comprising the first material, the heating member comprising a filament attached to first and second locations of the coil.

42. (Currently Amended) A vaso-occlusive device for treating a site within a patient's vasculature, comprising:

a first material which, if the device has been detached from a delivery catheter and deployed at a treatment site in the patient's vasculature, may be heated by application of energy transmitted by an ~~source of~~ energy emitting element located external to the patient; and

a second material having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the device if the first material is heated by energy transmitted by the external energy ~~source~~ emitting element,

wherein the second material is embedded in one or more portions of the device, such that, if the device is detached from a delivery catheter and implanted at the treatment site when heated by energy transmitted by the external energy ~~source~~ emitting element, and thereafter allowed to cool at the treatment site, the one or more portions are at least partially melted and fused together to thereby stabilize the vaso-occlusive device in a deployed configuration.

REMARKS

Claims 1-4, 6-14, 16, 18-19, 25-26 and 37-42 are pending in this application, of which claims 1-3, 7, 18-19, 25-26, 37-38 and 42 are currently amended, claims 4, 9, 14, 16, 26 and 40 are currently withdrawn from examination pursuant to a previous election, but are to be reinstated and allowed upon allowance of a respective generic (and any intervening) claim from which the respective withdrawn claim depends. Claims 5, 15, 17, 20-24, 27-36 are cancelled. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement including the prosecution history, namely office actions and responses, of related US Patent Application S.N. 10/669,543. Applicant respectfully requests consideration of the references cited in the information disclosure statement.

Claim Rejections - 35 U.S.C. §103

Claims 1-3, 6-8, 10-13, 37 and 39-42 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent No. 5,853,418 ("Ken") in view of U.S. Patent No. 5,108,407 ("Geremia") and in further view of U.S. Patent No. 6,280,457 ("Wallace"). In particular, the Examiner has asserted that, in view of Geremia and further view of Wallace, it would have been obvious to one skilled in the art to construct the coil device described in Ken with a bioactive agent that is release or activated from the rest of the device when the device is heated to release the coil from the delivery catheter. Applicant respectfully disagrees in view of the amended claims.

The Supreme Court has recently addressed the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. ___ (2007), in which the Court reiterated the requirement that a rejection on "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (KSR at page 14 of the slip opinion), and further that a "fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning. (KSR at page 17 of the slip opinion). While not specifically addressed by the Supreme Court in KSR, the prior art reference (or references when combined) must teach or suggest all the claim limitations (See MPEP §2143).

Independent claims 1, 37, and 42 each have been amended to recite a first material which, if the device is detached from a delivery catheter and implanted at a treatment site, may be heated by application of energy transmitted by an energy emitting element located external to the patient, and a bioactive agent (claims 1 and 37) or second material (claim 42) which, if the device is detached from a delivery catheter and implanted at a treatment site, is released (claim 1) or activated (claim 37) or partially melt or fuse together (claim 42) from the device upon heating the device by application of energy transmitted by said external energy emitting element.

Ken discloses releasing a vaso-occlusive coil in a treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62). Geremia discloses releasing a vaso-occlusive coil into the treatment site by heating an adhesive bond that joins the coil to the delivery device (Col 4, lines 14-15). Even if Geremia may be properly combined with Ken, such combination would still not teach or suggest that the **coil** of Ken would be made of a

material that acts as a heating member after the device is detached from a delivery catheter and implanted in a treatment site in the patient's vasculature by application of energy transmitted by an energy emitting element located external to the patient. Both of these references disclose releasing a coil from a delivery device by detaching a severable joint; **neither reference discloses or suggests heating the already detached and implanted** coil application of energy transmitted by an energy emitting element located external to the patient, as recited in independent claims 1, 37 and 42. More particularly, the application of electricity or heat as disclosed in Ken and Geremia respectively, is to a severable ***joint*** that ***releases the coil*** from a delivery device into the treatment site and **not** to the coil itself to release or activate bioactive agents (claims 1 and 37) or partially melt and fuse together second material (claim 42) after the coil is detached from a delivery catheter, as recited in amended independent.

It was stated in the office action that, in view of Geremia and further view of Wallace, it would have been obvious to *"detach the coil from the device by heating and braking* (sic) *an adhesive bond between the coil itself and the rest of the device…and as further taught by Wallace et al., to provide the coil with a polymeric coating having a bioactive agent in order to improve the vaso-occlusion treatment"* (Emphasis added). As indicated in the disclosure of Geremia, the reason to apply heat to its occlusion device is to detach the coil from the pusher wire by breaking the adhesive bond. Wallace discloses a vaso-occlusive device comprising an inner core covered with a polymeric fiber, wherein the polymeric fiber covering may be used as a carrier for bioactive molecules (Col 12, lines 4-14). There is no reason to continue heating the device of Geremia after the coil is detached, as recited in independent claims 1, 37, and 42, even if combined with Wallace, because there is no

disclosure in Wallace that the bioactive agent carried by its device of Wallace is released or activated by heat. Wallace does not teach or suggest that the bioactive agent may be released or activated from the polymer device into the treatment site by the application of energy transmitted by an energy emitting element located external to the patient to heat the device after the device has been detached from a delivery catheter and implanted at the treatment site. Nor does Wallace teach or suggest melting and fusing the material to stabilize the vaso-occlusive device.

Even if a person skilled in the art would consider modifying the device of Ken, in view of Geremia and in further view of Wallace, the resulting device would be of an occlusion coil comprising bioactive agents that maybe detachable from a pusher wire by the application of heat, but not having the bioactive agent being activated or released by heating after the device is detached. The combination of cited references would not render the results of all the claims limitations of independent claims 1, 37, and 42, absent hindsight in view of the present application.

For at least these reasons, Applicant respectfully submits that independent claims 1, 37 and 42, as well as claims 2-3, 6-8, 10-13, and 39-41 which depend therefrom, are allowed over Ken, Geremia and Wallace, and requests withdrawal of the §103 claim rejections.

Additionally, claims 7, 18, 19, 25 and 38 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ken in view of Geremia, in further view of U.S. Patent Wallace and *in still further view* of U.S. Patent No. 6,059,815 ("Lee"), a combination of four separate references. In particular, the Examiner has stated that, in view of Geremia, in further view of Wallace, and in still further view of Lee, it would have been obvious to one

skilled in the art to construct the coil device described in Ken comprising a highly resistive or ferrous material with a bioactive agent that is detached from the rest of the device by RF and magnetic inducing heating. Applicant respectfully disagrees.

As demonstrated above, neither Geremia nor Wallace may be properly combined with Ken to result in the presently claimed invention, and there is no reason other than hindsight to further combine Lee. Lee discloses an aneurysm occlusion device that is released by laser, RF or magnetic inductive heating, which, again, ***releases the coil*** from the delivery device into the treatment site. However, claims 7, 18, 19 and 25 recite the ***release of a bioactive agent***, and claim 38 recites the ***activation*** of a bioactive agent, upon magnetically inducing heating of the device ***after the device is detached from a delivery catheter and it is implanted*** at the treatment site. Furthermore, neither of the cited references suggests applying magnetically inducing heating to the device after the detachment from the delivery catheter is performed to then, release or activate bioactive agents, absent hindsight in view of the present application.

Magnetic resonance imaging systems are used for imaging of a body and they are not normally used to produce heat in a body, since the production of heat in a body when undergoing an MRI is known as an undesirable and potentially dangerous side effect if the body contains certain amount of highly resistive material. A person skilled in the art would not normally look to using an MRI system for heating an implanted device. Therefore, there is no reason, absent hindsight, to combine the cited references to heat an implanted device using an MRI system to activate or release a bioactive agent as recited in claims 7, 18, 19 and 25.

For at least these reasons, Applicant respectfully submits that independent claims 7, 18, 19, 25 and 38, are allowed over Ken, Geremia, Wallace and Lee, and requests withdrawal of the §103 claim rejections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully submits that all pending claims are allowable over the cited references. Accordingly, a notice of allowance is earnestly solicited. If the Examiner believes that a further telephone interview could expedite resolution of any remaining issues, he is welcome to call the undersigned at the below-listed number.

Respectfully submitted,
VISTA IP LAW GROUP LLP

Dated: 10-25-07

By: David T Burse
David T. Burse
Reg. No. 37,104

Customer Number
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